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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,553	01/31/2005	Ferenc Buzsaky	1103326-0786	1185
7470	7590	09/28/2007	EXAMINER	
WHITE & CASE LLP PATENT DEPARTMENT 1155 AVENUE OF THE AMERICAS NEW YORK, NY 10036			AHMED, HASAN SYED	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			09/28/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/523,553

Applicant(s)

BUZSAKY, FERENC

Examiner

Hasan S. Ahmed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2 and 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

- Receipt is acknowledged of applicant's amendment, which was filed on 16 July 2007.
- The 35 USC 103 rejection over U.S. Patent No. 6,827,947 is withdrawn in view of the remarks.

\* \* \* \* \*

### ***Election/Restrictions***

After further consideration and in view of applicants' remarks of 16 July 2007, Groups III and IV are hereby rejoined. Claims 1, 2, and 10-16 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, for the reasons stated in the restriction requirement of 25 September 2006.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Petereit et al. (European Journal of Pharmaceutics and Biopharmaceutics, vol. 41, no 4, pages 219-228).

Petereit et al. disclose polymethacrylate and glycerol monostearate (GMS) formulations (see summary) comprising:

- the pharmaceutical core comprising a pharmaceutically active ingredient of instant claim 3(a) (see section 2.7);

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- the film coat comprising an ethyl acrylate/methyl methacrylate copolymer of instant claim 3(b)(i) (see section 2.1);
- the film coat comprising the GMS of instant claim 3(b)(ii) (see section 2.3);
- the surface active agent of instant claim 3(b)(iii) (see section 2.4, tables 4-6);
- the lipid (GMS) of instant claim 3 (see section 2.3); and
- the modified release formulation of instant claim 5 (see section 2.1).

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 4, and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. in view of Hölzer et al. (WO 02/058677).

Petereit et al. disclose polymethacrylate and glycerol monostearate (GMS) formulations (see above).

Petereit et al. explain that combining the disclosed ingredients into one formulation is beneficial because the amount of glidant required is reduced, and suspensions are stabilized (see summary).

The Petereit et al. reference differs from the instant application in that it does not teach the plurality of beads of instant claim 4, the modified release composition with a core comprising the active ingredient for treatment of cardiovascular disease of instant

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claim 6, the beta-blocking adrenergic agent of instant claim 7, the metoprolol of instant claim 8, or the metoprolol salt of instant claim 9. However, these formulations are well known in the art, as shown by Hölzer et al.

Hölzer et al. teach a film coated pharmaceutical composition (see abstract) with a core comprising:

- the sorbitan ester of instant claims 3 and 4 (see page 11, line 2);
- the plurality of beads of instant claim 4 (see page 6, line 25);
- the active ingredient for treatment of cardiovascular disease of instant claim 6 (see page 7, line 22);
- the beta-blocking adrenergic agent of instant claim 7 (see page 7, line 23);
- the metoprolol of instant claim 8 (see page 7, line 29); and
- the metoprolol salt of instant claim 9 (see page 8, line 3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the disclosed ingredients into one formulation, as taught by Petereit et al. in view of Hölzer et al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because of advantages such as a reduction in the amount of glidant required, and stabilized suspensions, as explained by Petereit et al.

\* \* \* \* \*

***Response to Arguments***

Applicant's arguments filed 16 July 2007 regarding 35 USC 102 have been fully considered but they are not persuasive.

Applicants argues that, "[a]ccording to the amended claims, GMS cannot be both the anti-sticking agent and the surface active agent..." See remarks, page 7.

Examiner respectfully disagrees. The claims as currently constructed do not preclude GMS from acting as both an anti-sticking agent and as a surface active agent.

★

***Correspondence***

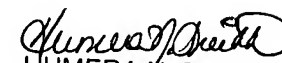
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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HUMERA N. SHEIKH  
PRIMARY EXAMINER